OCT 2 4 2000

K 002492

Sterling Medivations, Inc.
180 Ferndale Road South
Wayzata, Minnesota 55391
952-473-7971 (voice)
952-473-4758 (fax

510(k) SUMMARY

Date Submitted: September 19, 2000

Submitter: Sterling Medivations, Inc. 180 Ferndale Road South, Wayzata, MN 55391
Company Phone 952-473-7971, Company Fax 952-473-4758

Contact: Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 650-949-0470, Applicant Fax 650-949-0342

Trade Name of Device: Simplicity™ Soft Infusion Set for use with the MiniMed® infusion pumps and MiniMed medication reservoirs (model MMT-103).

Common Name of Device: Intravascular administration set.

Classification Name: Percutaneous intravascular catheter.

Predicate Device: The predicate device for Sterling's Simplicity Soft Infusion Set is the Maersk Medical Contour™ Infusion Set, K991759 that is currently supplied to and sold by MiniMed® as the MiniMed Silhouette® Infusion Set.

Decription of the New Device: Sterling Medivation Inc.'s ("SMI") Simplicity™ Soft Infusion Set is designed for use by people with diabetes to provide a means to infuse insulin subcutaneously when the device is attached to a MiniMed® medication reservoir (model MMT-103) or equivalent means.

The Simplicity™ Soft Infusion Set proposed for commercial distribution is similar in all significant respects to the existing MiniMed Silhouette Infusion Set and it has the same intended use.

The device consists of four main parts: (1) an infusion catheter made from FEP, (2) an infusion hub that provides the patient the capability of disconnecting the connecting tube from the infusion catheter, (3) a connecting tube and (4) a female Luer pump connector.

The Simplicity Soft Infusion Set is an infusion administration set, connecting to a medicine reservoir syringe (such as the MiniMed reservoir, model 103, that is placed in an external infusion pump such as the MiniMed insulin pump) and inserted in the subcutaneous tissue of a patient.

The administration set attaches to the reservoir/syringe by means of a female Luer connector, and subcutaneously in the patient through an indwelling catheter made of Fluorinated Ethylene Propylene (FEP). The connecting tubing is made from a polyethylene tube.

The 25 gauge-indwelling catheter is introduced into the subcutaneous tissue by a removable 27 gauge introducer needle formed from a solid lumen made of AISI 304 stainless steel. The introducer needle is removed and a connector needle is attached to the hub fixed to the indwelling catheter. This connector needle mates with the indwelling catheter forming a seal that permits the infusion of medication without leakage. The connector needle is made from AISI 304 stainless steel and it is connected to the connecting tubing. The connector tubing proximal end is attached to a female Luer connector for attachment to the medicine reservoir.

Intended Use of the New Device: The intended use of the Simplicity Soft Infusion Set is to provide a means to infuse insulin subcutaneously when the device is attached to a MiniMed medication reservoirs (model MMT-103).

Comparison of the Technological Features of the New Device and Predicate Device:

The Simplicity Soft Infusion Set proposed for commercial distribution is similar in all significant respects to the existing Maersk Medical Contour™ Infusion Set, K991759 that is currently supplied to and sold by MiniMed® as the MiniMed Silhouette® Infusion Set.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent and it has the same intended use as the Maersk Medical Contour™ Infusion Set, K991759 that is currently supplied to and sold by MiniMed® as the MiniMed Silhouette® Infusion Set.

The differences that exist between the new and predicate device are as follows:

1. The new device has a connecting tube of Polyethylene and the predicate device has a connecting tube of co-extruded connecting tube Polyethylene ID and PVC OD.

2. The new device uses a connecting tube to the hub interface of PVC shrink tube attached to each end and solvent bonded with Loctite 4011. The predicate device uses a connecting tube to hub interface of solvent bond.

3. The new device has a plug made of Fluorinated Ethylene Propylene (FEP). The predicate device has a plug made of PVC.

Performance Data Supporting Substantial Equivalence: To prove substantial equivalence both Simplicity Soft Infusion Set and Maersk Medical Contour™ Infusion Set, K991759 that is currently sold by MiniMed® as the MiniMed Silhouette® Infusion Set meet the requirements of:

- CDRH 21 C.F.R. Section 880.54400 Intravascular administration set,
- ISO 10555 Sterile, single use intravascular catheters (Part 1: General Requirements)
- ISO 10555 Sterile, single use intravascular catheters (Part 5: Peripheral Catheters).
- ISO 9626: 1991 Stainless steel needle tubing for the manufacture of medical devices.
- ISO 594-1:1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements,
- ISO 594-2:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
- ISO 11607: 1997 Packaging for terminally sterilized medical devices
- ISO 8537: 1991 Sterile single use syringes, with or without needle, for insulin.
- ISO 11135:1994 Medical devices -- Validation and routine control of ethylene oxide sterilization
- ISO 11138-2:1994 Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization
- The design process adhered to is the Center for Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001.

Signed,

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2000

Mr. Joel S. Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
180 Ferndale Road South
Wayzata, Minnesota 55391

Re: K002492
Trade Name: Simplicity Soft Infusion Set
Regulatory Class: II
Product Code: FPA
Dated: September 20, 2000
Received: September 25, 2000

Dear Mr. Douglas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002492

Indications for Use

The intended use of the Simplicity Soft Infusion Set is to provide a means to infuse insulin subcutaneously when the device is attached to a MiniMed® medication reservoir (model MMT-103).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices
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